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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,062	09/23/2003	Robert Murtfeldt	59249-154 (INSL-150)	2741

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EXAMINER	
WHALEY, PABLO S	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,062	MURTFELDT ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks, filed 05/03/2007, have been fully considered. The following rejections and/or objections are maintained, newly applied, or withdrawn for the reasons set forth below. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

An action on the merits of claims 1-11 follows.

ABSTRACT

The amended abstract is acceptable.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "wherein the user information includes at least one of, the age..., the type..., an amount..., the duration and intensity of exercise in which the user intends to engage in the immediate future and at least one of the first and second correction factors is

variable dependent upon at least one aspect of the user information". Applicant amendment did not clarify the issues. It remains unclear whether this claim is intended to further limit said user information, correlation factors, or both. Clarification is requested. Furthermore, it is noted that this claim recites passive language (i.e. to ingest, to engage) which is interpreted as an intended use.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, and 10 remain rejected under 35 U.S.C. 102 (b) as being anticipated by Albisser et al. (Medical & Biological Engineering & Computing, 1986, Vol. 24, p.577-584).

Applicant's arguments, filed 05/03/2007, that Albisser et al. do not teach a range of suggested doses presented to a user are not persuasive for the following reasons.

As set forth in the previous office action mailed 11/3/2006, Albisser et al. present a range of specific insulin dosages for improving patient condition [Table 2], as in instant claims 1(c) and 2. Specifically, Albisser et al. teach at least two specific doses (i.e. SAI and IAI doses) that cover final recommended insulin dosages that should be administered at two different times (i.e.

breakfast and dinner) for a plurality of treatment scenarios. As applicant has not provided a limiting definition for "range" in the specification that would server to distinguish the instant claims from the teaching of Albisser et al., the Examiner has broadly and reasonably interpreted the instant claims to encompass the teachings of Albisser et al. For these reasons, the Examiner maintains that Albisser et al. teach all aspects of the instantly rejected claims. This rejection is therefore maintained and reiterated.

Albisser et al. teach methods and algorithms for insulin dosage adjustment for diabetic patients [Abstract]. More specifically, Albisser et al. teach the following aspects of the instantly claimed invention:

- Calculating a plurality of distinct doses of insulin (IAID, IAIB, SAIB, SAID) using patient blood glucose information and dose-adjusting algorithms [p.578, Col. 1, ¶ 4 and Col. 2], as in claim 1(a) and (b).
- Blood glucose values on "day 0" (i.e. current) [Fig. 1] and optimized glucose levels (i.e. desired) [Fig. 2], as in claim 1 (a).
- Presenting a range of specific insulin dosages for improving patient condition [Table 2], as in instant claims 1(c) and 2.
- Equations comprising specific doses corrected by the addition/subtraction of quotient comprising the Σ of glucose values and sensitivity factors (S_i) [p. 578, Equations (1)-(4)], which is a teaching for "correction factors" as in claims 3 and 4. Furthermore, any correction "quotient" is inherently a teaching for a percentage, as in claim 7.
- A plurality of identical and different sensitivity factors (S_i) [p.578, Col. 2, ¶ 2], as in claims 5 and 6.
- User information comprising glucose levels with upper and lower boundaries based on future carbohydrate amounts ingested after meals [Table I and II], as in claims 9 and 10.

Claims 1-2 remain rejected under 35 U.S.C. 102 (b) as being anticipated by Lehmann et al. (Computer Methods and Programs in Biomedicine, 1996, Vol. 50, p.209-230).

Applicant's arguments, filed 05/03/2007, that Lehmann et al. do not teach a range of suggested doses presented to a user are not persuasive for the following reasons.

As set forth in the previous office action mailed 11/3/2006, Lehmann et al. present a screen which displays specific insulin dosages for improving patient condition [Fig. 5, Fig. 3, and Table 2], as in instant claims 1(c). Furthermore, Lehmann et al. teach a computer system that generates therapeutic advice and can recommend changes in timing or dosage of single injections, daily treatment plans, or long term treatment protocols [p. 210, Col. 2, ¶3] wherein the system could provide a number of different pieces of advice for any one set of patient data [p.218, Col. 1, ¶ 1]. Therefore, the method of Lehmann et al. inherently provides "ranges" of insulin dosages provided to the patient based on changing BG levels over time. As applicant has not provided a limiting definition for "range" in the specification that would server to distinguish the instant claims from the teaching of Lehmann et al., the Examiner has broadly and reasonably interpreted the instant claims to encompass the teachings of Lehmann et al. For these reasons, the Examiner maintains that Lehmann et al. teach all aspects of the instantly rejected claims. This rejection is therefore maintained and reiterated.

Lehmann et al. teach methods and a computer-based system (AIDA) for providing therapeutic advice and generating glycemic predictions in diabetic patients [Abstract]. More specifically,

Lehmann et al. teach the following aspects of the instantly claimed invention:

- Calculating a plurality of distinct doses of insulin using patient information and an automated insulin dosage advisor (AIDA) [Fig. 4] and [p.213, Col. 2, ¶ 2], as in claims 1(a), 1(b), and 2.
- Patient information comprising observed blood glucose (i.e. current) and predicted blood glucose levels (i.e. desired) [Fig. 2], as in claim 1 (a)
- Presenting a range of specific insulin dosages for improving patient condition [Fig. 5, Fig. 3, and Table 2], as in instant claims 1(c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 11 remain rejected under 35 U.S.C. 103(a) as being made obvious by Albisser et al. (Medical & Biological Engineering & Computing, 1986, Vol. 24, p.577-584), as applied to claims 1-7, 9, and 10, above, in view of Garg et al. (Diabetes Care, 1999, Vol. 22, No. 10, p.1708-1714).

Applicant's arguments, filed 05/03/2007, that Albisser et al. do not teach a range of suggested doses presented to a user are not persuasive for the reasons set for above. For these reasons, the Examiner maintains that Albisser et al. teach all aspects of the instantly rejected claims. This rejection is therefore maintained and reiterated.

Albisser et al. teach methods and algorithms for insulin dosage adjustment for diabetic patients [Abstract], as set forth above.

Albisser et al. do not specifically teach the limitation of "error rate of the blood glucose monitor", as in claims 8 and 11. Howerver, Albisser et al. do suggest simulation of errors in blood glucose estimation, absorption of food from the gut (i.e. ingested carbohydrate estimation), and errors in insulin administration [p.578, Col. 1, ¶ 1].

Garg et al. teach a *Glucowatch Biographer* for measuring blood glucose levels in diabetes patients [Fig. 1]. Furthermore, Garg et al. teach the calculation of mean absolute relative error rates between the glucose monitor and reference glucose values [p.1710, Col. 1, ¶ 3] expressed as percentages [Table 1], as in claims 8 and 11. In addition, Garg et al. teach error rate percentages calculated for hyperglycemic and hypoglycemic blood glucose ranges [p.1711, Col. 2, ¶ 2].

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to combine the error rate calculations taught by Garg et al. with the insulin dosage adjustment algorithms taught by Albisser et al., where the motivation would have been to improve system precision and data correlation, as taught by Garg et al. [p.1710, Col. 3, ¶ 3 and ¶ 4], resulting in the practice of the instant claimed invention. Further motivation to combine the above references is provided by Albisser et al., who teaches the need to simulate insulin dosage in relation to dietary carbohydrate levels in individuals with hypoglycemia [p.582, Col. 1, ¶ 2]. One of skill in the art would have had a reasonable expectation of successfully using the

error rates of Garg et al. with the insulin dosage algorithm of Albisser et al. as both Garg et al. and Albisser et al. teach methods for correcting glucose data.

CONCLUSION

No claims are allowed.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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